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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/087,377	03/01/2002	Qingsheng Zhu	279.407US1	3372
21186	7590	10/04/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.			ALTER, ALYSSA M	
P.O. BOX 2938			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402			3762	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,377

Applicant(s)

ZHU ET AL.

Examiner

Alyssa M Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/01/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/01/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/19/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1- 10 are drawn to an apparatus with a coronary sinus lead, classified in class 607, subclass 122.
- II. Claims 11-25 are drawn to a method of measuring a myocardium temperature, classified in class 607, subclass 122.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method could utilize another type of lead, such as a catheter, with dimensions capable of being implanted into the coronary sinus.

During a telephone conversation with Catherine I. Klima-Silberg on September 21, 2004 a provisional election was made without traverse to prosecute the invention of process, claims 11-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 11, it is unclear if "at least one thermal sensor" (line 4) and "one or more thermal sensors"(lines 8 and 9) are the same or different.
2. Claims 13-16 recite the limitation "the first thermal sensor" in line 1 of claim 13. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests claim 13 be dependent on claim 12, not claim 11 as the claim states.
3. Claims 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 19, the steps "placing the implantable lead and at least one" (line 8) and "positioning the first" (lines 9 and 10) seems redundant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 11-12 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Salo (US Patent Publication 20030125774). Salo discloses a method and apparatus for monitoring left ventricular work or power through an implantable lead system that passes through the right atrium and coronary sinus. Figure 2 displays the positioning of the lead within the coronary sinus. Although the Salo device does not measure the myocardium temperature, it does measure the "averaged blood temperature in the coronary sinus" (page 4, paragraph 41). Therefore it is inherently capable of measuring the myocardium temperature.

As to claim 12, figure 2 shows the placement of two thermal sensors, 9 and the alternative 8.

As to claims 16 and 17, "the electrical impulses delivered to the electrode 16 can be adaptively adjusted by the detector/energy delivery system 2 based on temperature outputs from the thermal sensor 9. The thermal sensor 9 of a system according to the present invention can measure the temperature of the blood returning through the coronary sinus after having passed through myocardial tissue" (page 4, paragraph 44). Since the device can measure the temperature, it can inherently measure the temperature change.

As to claim 18, "The difference between the current temperature and a long-term average temperature could also be used as an activity indicator, since increased temperature with a relatively short rise time (on the order of seconds or minutes) would

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be indicative of increased activity"(page 4, paragraph 48). Therefore a change in activity, would inherently change the functional status of the heart

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 13-14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo (US Patent Publication 20030125774). Salo teaches the invention substantially as claimed, but fails to teach the insertion of a sensor into the right atrium. However, since "the sensing catheter includes at least one thermal sensor at a distal end of the sensing catheter" (page 1, paragraph 7), placing an additional sensor on a portion of the that passed through the right atrium would have been obvious, since it is well known in the art to place a sensor in the right atrium in order to monitor and/or pace the heart. For example, Alt (US 4,688,573) includes a temperature sensor with an electrode in the right atrium area. Therefore by placing a thermal sensor in the right atrium and a thermal sensor in the coronary sinus, temperature can be measured.

Allowable Subject Matter

1. Claims 15 and 20-25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of

the limitations of the base claim and any intervening claims.

Drawings

The drawings are objected to because 106 leads to the left atrium, while the specification claims it leads to the right atrium. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (703) 605-1156. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

[Signature]
JEFFREY D. JASTRZAB
PRIMARY EXAMINER
9/29/04